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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/824,095      | 04/13/2004  | Eiichi Ueda          | KON-1870            | 6153             |

20311 7590 02/16/2007  
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| EXAMINER |
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PERREIRA, MELISSA JEAN

|          |              |
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| ART UNIT | PAPER NUMBER |
|----------|--------------|

1618

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE  | DELIVERY MODE |
|--|------------|---------------|
| 3 MONTHS                               | 02/16/2007 | PAPER         |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/824,095             | UEDA ET AL.         |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Melissa Perreira       | 1618                |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 January 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

1. Claims 1-26 are pending in the application.
2. Any rejections from previous office actions that have not been reiterate in this office action are obviated
3. The declaration under 37 CFR 1.132 filed 1/3/07 is insufficient to overcome the rejection of claims 1-26 based upon the rejections as set forth in the last Office action because: The reference of Mackaness et al. anticipates and broadly teaches of the use of organic solvents such as ethyl acetate and dioxane, etc. in the preparation of contrast agents of the disclosure where the reaction would not be carried out in a chlorinated solvent (column 3, lines 43-47). It is inadequate to provide information on the preparation of contrast agents via the method of Mackaness et al. utilizing only example 1 which contains chlorinated solvent as the disclosure anticipates the use of other, non-chlorinated solvents in the preparation of the contrast agents of Mackaness et al. The preparation of the contrast agents in ethyl acetate, for instance, would generate contrast agents with no chlorinated solvent and thus encompasses the contrast agents of the instant claims.
4. The reference of Klaveness et al. anticipates and broadly teaches of the use of organic solvents such as methanol, ethanol, etc. in the preparation of contrast agents of the disclosure where the reaction would not be carried out in a chlorinated solvent (column 8, lines 46-52). It is inadequate to provide information on the preparation of contrast agents via the method of Klaveness et al. utilizing only example 1 which contains chlorinated solvent as the disclosure anticipates the use of other, non-

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chlorinated solvents in the preparation of the contrast agents of Mackaness et al. The preparation of the contrast agents in ethanol, for instance, would generate contrast agents with no chlorinated solvent and thus encompasses the contrast agents of the instant claims. In regards to the argument that the liposome of Klaveness et al. does not provide unilamellar vesicles, Klaveness et al. describes that the passing of the liposome suspension through a filter (around 1 micron pore size) provides a multilamellar and unilamellar liposome via stripping away the outer layers of lipid and that a large proportion of unilamellar liposome is acceptable, particularly because they provide higher encapsulation capacity than multilamellar liposomes (column 9, lines 39-50).

### ***Response to Arguments***

5. Applicant's arguments, see response, filed 1/3/07, with respect to claim objections of claims 4 and 7 have been fully considered and are persuasive. The rejection of claims 4 and 7 has been withdrawn.

6. Applicant's arguments, see response, filed 1/3/07, with respect to claims rejections 35 U.S.C. §112 have been fully considered and are persuasive. The rejection of claim 25 has been withdrawn.

7. Applicant's arguments, see response, filed 1/3/07, with respect to claims rejections 35 U.S.C. §112 have been fully considered and are persuasive. The rejection of claim 10-12 has been withdrawn.

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8. Applicant's arguments filed 1/3/07 have been fully considered but they are not persuasive.

***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-4,13,17 and 18 rejected under 35 U.S.C. 102(b) as being anticipated by Mackaness et al. (US 4,192,859) as stated in the office action mailed 10/25/06.

11. As the declaration is insufficient to overcome the rejection. See above.

12. It is respectfully pointed out that instant claims 2 and 17 are product-by-process limitations. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed Cir. 1985). See MPEP 2113.

***Claim Rejections - 35 USC § 103***

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

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the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 1-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klaveness et al (US 5,676,928) in view of the combined disclosures of Na et al. (US 5,326,552) and Otake et al. (US2004/0099976A1) as stated in the office action 10/25/06.

15. As the declaration is insufficient to overcome the rejection. See above.

16. It is respectfully pointed out that instant claims 2,9 and 17-20 are product-by-process limitations. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed Cir. 1985). See MPEP 2113.

17. It is noted that applicant failed to provide a response for the nonstatutory double patenting rejections and therefore the rejections are maintained for reasons provided in the previous office action mailed 10/25/06.

***Conclusion***

No claims are allowed at this time.

18. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

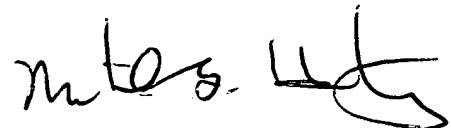
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa Perreira whose telephone number is 571-272-1354. The examiner can normally be reached on 9am-5pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melissa Perreira  
February 12, 2007

A handwritten signature in black ink, appearing to read "m. g. hartley", with a stylized flourish at the end.

MICHAEL G. HARTLEY  
SUPERVISORY PATENT EXAMINER



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